CAHAN San Diego
California HEALTH ALERT NETWORK

To: CAHAN San Diego Participants
Date: September 17, 2013

Continuing Nationwide Shortage of Tuberculin Skin Testing Antigen

This CAHAN updates the August 28, 2013 alert on the nationwide tuberculin skin testing **(**TST) antigen shortage and notifies local providers regarding changes in routine tuberculosis (TB) screening at County of San Diego Health and Human Services Agency (HHSA) Public Health Centers (PHCs).

The ongoing national shortage in TST antigens has caused reduced supplies throughout the community. In order to assure resources are available for groups at increased risk for TB, HHSA PHCs will no longer provide routine TB testing for individuals with health insurance. Routine testing includes those coming for pre-employment or employment testing, volunteers, school requirements, or licensure and childcare requirements. Those without health insurance will be tested based on a risk assessment performed at HHSA PHCs.

Recommendations for San Diego Providers:

1. Do not test those who are not at risk for TB. Allocate TST to priority indications, such as testing persons recently exposed to an active TB case, newly arrived immigrants and refugees, HIV-infected individuals and others with risk factors for exposure and progression to active TB disease.[1,2]

2. Do not routinely skin test elementary, high school or college students for school entry. There is no state mandate requiring TST entry screening. Use symptom screening or risk assessment as a basis for testing as needed.

3. Defer routine serial testing in settings with a low likelihood of TB exposure until the TST antigen supply improves, consulting with occupational health professionals when applicable. Switching products or methods for populations that require serial TB screening might make serial changes in test results difficult to interpret. Apparent conversions of results from negative to positive or reversions from positive to negative could be caused by inherent inter-product or inter-method discordance.[3, 4]

4. Use interferon gamma release assays (IGRAs) as diagnostic aids in *Mycobacterium tuberculosis* infection. Two FDA-licensed IGRA blood tests are available to detect *M. tuberculosis* infection. The blood tests have the same indications as the skin tests and may be used in all situations in which TST is recommended despite preferences indicated in latest CDC guidelines.[3] The use of either IGRA or TST is acceptable medical and public health practice. Clinicians who use the IGRA blood tests should be aware of criteria for test interpretation.[3]

5. Consider using IGRA blood tests for health care workers and others who require screening under California Code of Regulation, Title 22. Effective May 30, 2013, any TB test that is FDA licensed and CDC recommended meets the screening requirement. IGRA blood tests no longer require a grant of program flexibility from CDPH Licensing & Certification.[5] Use caution when individuals require serial tests as noted above.

6. Recognize that when active TB disease is suspected, the results from TST or an IGRA blood test might not be needed when findings such as chest radiography and mycobacterial smears and cultures are sufficient for confirming or excluding the TB diagnosis.[6]

7. Contact Sanofi at 1-800-VACCINE (822-2463) or JHP at 1-877-547-4547 to obtain updates on TST antigen supply**.**

8. Contact local representatives of the test manufacturers to learn where blood-based TB testing is locally available: Oxford Immunotec (manufacturer of TSpot TB ®) at 1-877-208-7768; or Qiagen (manufacturer of QuantiFERON ®) at 1-800-426-8157 or customerservice@cellestis.com. Some locations may be available to provide blood-testing service on a walk-in basis.

9. Assure staff members involved with obtaining samples for IGRA blood tests or reviewing test results are aware of emerging information about these tests. Staff should receive specific training from the test manufacturer on best practices. Failure to mix specimens correctly or to deliver them to a reference laboratory in a timely manner can influence results. It is also important to record quantitative results and not to accept results as "positive" or "negative." Consult with experts knowledgeable about IGRA blood testing when noting results that do not align with historical TST positivity rates in a given practice or institution, especially with high numbers of indeterminate or positive results.

The HHSA does not supply TST antigen to local providers. Patients should not be directed to HHSA clinics based on shortages in your practice, agency or organization. For more information or questions on specific patient management, please call the TB Control Branch at 619-692-8621.

References

[1] CDPH. Recommendations for responding to shortage of TB skin test antigens. August 13, 2013 letter to TB controllers. http://www.tbcontrollers.org/docs/TBDrugsAndBiologicsShortages/California_Recommendations_Responding_to_TB_Antigen_Shortage_081413.pdf Accessed September 16, 2013.

[2] CDC. Targeted tuberculin testing and treatment of latent tuberculosis infection. MMWR 2000;49(RR-6). http://www.cdc.gov/mmwr/PDF/rr/rr4906.pdf. Accessed September 16, 2013.

[3] CDC. Updated guidelines for using interferon gamma release assays to detect *Mycobacterium tuberculosis* infection — United States, 2010. MMWR 2010;59 (RR-5). http://www.cdc.gov/mmwr/pdf/rr/rr5905.pdf. Accessed September 16, 2013.

[4] CDC. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care settings, 2005. MMWR 2005;54(RR-17) http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf. Accessed September 16, 2013.

[5] CDPH. Regulatory Changes to Tuberculosis Screening and Testing. June 13, 2013 All facilities letter. http://www.cdph.ca.gov/certlic/facilities/Documents/LNC-AFL-13-15.pdf. Accessed September 16, 2013.

[6] CDC. Treatment of tuberculosis. MMWR 2003;52(RR-11). http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf. Accessed September 16, 2013.

Thank you for your continued participation.

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